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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/447,218 11/23/99 ABERG

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HM12/0323

EXAMINER

CRANE, L

ART UNIT

PAPER NUMBER

1623
DATE MAILED:

03/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/447,218

Applicant(s)
Aberg et al.

Examiner
L. E. Crane

Group Art Unit
1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 11/23/99 (Preamdt A and IDS)

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 34-40 is/are pending in the application.

Of the above claim(s) is/are withdrawn from consideration.

☐ Claim(s) is/are allowed.

☒ Claim(s) 34-40 is/are rejected.

☐ Claim(s) is/are objected to.

☐ Claim(s) are subject to restriction or election requirement.

[x] Claims 1-33 and 41-47 have been cancelled.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s): 4 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

- 5 Claims **1-33 and 41-47** have been cancelled, no new claims have been entered, and the preliminary amendments and Information Disclosure Statement (IDS) filed November 23, 1999 have been entered.

10 Applicant is respectfully requested to include a complete "header" and "footer" on each page of all PTO-1449's submitted henceforth in order to facilitate processing and to insure that separated pages can be easily identified and reunited with the file.

Claims **34-40** remain in the case.

- 15 Claims **35-37 and 40** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 20 Claims **35, 36 and 37** lack proper antecedent basis in claim **34** because the noted claims refer to side effect avoidances and no side effect avoidance is presently noted as a limitation in claim **34**.

- 25 In claim **40**, line 2, the acronym "DCL" is noted but has not been accompanied by a common or more preferably an IUPAC chemical name. Applicant is respectfully requested to identify by IUPAC chemical name all active ingredients with the acronym following in parentheses in the first independent claim where the compound is

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identified; [e.g. -- 3'-deoxy-3'-azidothymidine (AZT) --.

Subsequent use of the acronym is then freely available. Applicant may directly address this rejection by simply adding the acronym -- (DCL) -- in parentheses after the common name in claim 34.

5 The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 “A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

15 Claims 34-40 are rejected under 35 U.S.C. §103(a) as being unpatentable over Berkow et al. (PTO-892 ref. R) in view of Villani et al. '716 (PTO-1449 ref. AE).

 The instant claims are directed to the treatment of urticaria (aka hives) by the administration of an effective dosage of descarboethoxyloratadine to a patient in need thereof.

20 Berkow et al. discloses at p. 333, beginning in the third line under “**Treatment**,” that “[s]ymptoms [of urticaria] usually can be relieved with an oral [dose of an] antihistamine”

25 Villani et al. '716 discloses at column 1, lines 39-46 that descarboethoxyloratadine (DCL) and closely related compounds are effective antihistamines with the advantage of low CNS-related side effects, i.e. that DCL and relatives are non-sedative.

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The findings that

- i) Villani et al.'s teaching that DCL and related compounds are known to be effect antihistamines,
- ii) the teaching by applicant that DCL has the expected effect in the treatment of urticaria (hives) as predicted by Berkow et al., and
- iii) the failure of applicant to establish any unexpected results, when taken together establish that the instant combination of references renders the instant claimed subject matter lacking in any patentable distinction in view of the noted prior art.

Therefore, the instant claimed of treating urticaria by the administration of DCL would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as closely related prior art which shows the state of the relevant prior art.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **703-308-4639**. The examiner

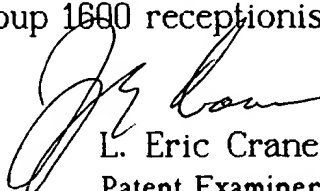
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can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-**308-1235**.

10 LECrane:lec
03/21/00


L. Eric Crane
Patent Examiner
Group 1600